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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,926	04/02/2004	Chien-Hsuan Han	21077-8	9426

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
12/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,926	HAN ET AL.	
	Examiner	Art Unit	
	NISSA M. WESTERBERG	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 - 24* is/are pending in the application.

4a) Of the above claim(s) *18,19 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 - 17, 20, 21, 23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II with species of a racemic mixture of baclofen and a capsule dosage form in the reply filed on October 30, 2007 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 13 – 24 are pending. Claims 18, 19 and 22 are withdrawn as being drawn to the non-elected invention. Claims 13 – 17, 20, 21, 23 and 24 are currently under examination.

Claim Rejections - 35 USC § 112 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13 – 17, 20, 21, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 13 recites

"wherein the ratio of said immediate release component to said controlled release component is from about 1:10 to about 10:1." No indication is given in the claims as to what information is used to calculate the ratio. For example, the ratio could be based on the weight of active ingredient in each component or the total weight (including the weight of any other ingredients such as excipients present) of the immediate and controlled release component. Therefore the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13 – 16, 20, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (US Patent 4,780,463).

Sunshine et al. discloses pharmaceutical compositions comprising a skeletal muscle relaxant and a non-steroidal anti-inflammatory drug (NSAID) (col 1, ln 16 – 19). Table III (bottom cols 11 and 12) lists centrally acting skeletal muscle relaxants, including baclofen, as well as the usual unit dose for each muscle relaxant. The usual unit dose for baclofen is 5 – 20 mg. Table IV (col 16 and col 17, ln 30 – 37) provides illustrative examples of unit does forms capsules. Compositions comprising an immediate and a sustained release component are denoted by an asterisk in the table. A number of skeletal muscle relaxants are exemplified as being administered in a unit dosage form with both an immediate and sustained release component. In these compositions, the ratio based on weight of skeletal muscle relaxant present in the immediate and sustained release components is 1:1. When the compositions are formulated with a sustained release form, the capsules can contain an impregnated or encapsulated porous polymeric matrix (col 17, ln 53 – 63).

The claims recite limitations as to the *in vitro* dissolution profile of the composition. Patentability of compositions is determined by the components of the compositions. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to

the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

No example of a composition comprising baclofen with both an immediate and sustained release component is provided but the equivalency of baclofen to skeletal muscle relaxants that are used in compositions comprising both an immediate and sustained release component is taught. The teachings of Sunshine et al. as to the use of equal amounts of skeletal muscle relaxants in a composition having both an immediate and sustained release component renders obvious to one of ordinary skill in the art at the time of the invention the claims of the instant application.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. as applied to claims 12 – 16, 20, 21 and 23 above, and further in view of Fara et al. (PGPub 2003/0031711).

As discussed above, Sunshine et al. discloses compositions comprising a skeletal muscle relaxant such as baclofen in an immediate and controlled release dosage form in which the ratio by weight of the active ingredient in the immediate and controlled release component is 1:1. Sunshine et al. does not disclose the stereochemical form(s) of the baclofen, although a structure is given in which a stereocenter is present.

Fara et al. discloses that baclofen can be administered in the form of mixtures of isomers such as racemates ([0034]). A racemate is also known as racemic mixture.

Given the knowledge of one of ordinary skill in the art as the existence of a racemic mixture of baclofen and the teachings of Fara et al. it would have been obvious to one of ordinary skill in the art to prepare a composition using a racemic mixture of baclofen.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. as applied to claims 12 – 16, 20, 21 and 23 above, and further in view of Patel et al. (US Patent 6,248,363).

As discussed above, Sunshine et al. discloses compositions comprising a skeletal muscle relaxant such as baclofen in an immediate and controlled release dosage form in which the ratio by weight of the active ingredient in the immediate and controlled release component is 1:1. Sunshine et al. discloses that capsules of the sustained release component can further contain impregnated or encapsulated polymeric matrix material but does not explicitly disclose that the capsule can further comprise discrete units.

Patel et al. teaches that enteric-coated delayed release oral dosage capsules, a type of controlled release dosage form, can contain pellets, beads or granules (col 43, ln 3 – 16).

The general teachings of Patel et al. make obvious to one of ordinary skill in the art a capsule with both an immediate and delayed release capsule further comprising discrete units given the teachings of Sunshine et al. that the sustained release component can further comprise encapsulated polymeric matrix materials. Therefore,

claim 24 would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Claims 13 – 17, 20, 21, 23 and 24 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571) 270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614